MONSANTO COMPANY
800 N. LINDBERGH BLVD.
St. Louis, Missouri 63167
http://www.monsanto.com

November 30, 2017

Document Processing Desk - 6(a)(2)
Office of Pesticide Programs
Document Processing Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Active Ingredient(s): tioxazafen
Product(s): Acceleron NemaStrike ST
EPA Registration Number(s): 524-624
Information which may be required under Section 6(a)(2) of FIFRA
Monthly Report for October 2017

To Whom It May Concern:

Monsanto Company submits the following reports pursuant to §6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §136(d)(a). This material is submitted to provide the Environmental Protection Agency additional information and it may or may not constitute data required to be submitted by a registrant pursuant to FIFRA. To the extent this information is not encompassed within the express language of §6(a)(2), this submission should in no way be construed as an express or implied admission by Monsanto Company that the legal authority of the Environmental Protection Agency to require submission of data pursuant to §6(a)(2) is broader than the express language of that section.

Monsanto was notified by a third party seed treater that three individuals alleged rash symptoms associated with exposure to tioxazafen. Two of these individuals were cleaning seed treater systems and a third was blowing down bagging equipment and sweeping the floor. All three developed rashes on their necks and torsos and were treated with steroids, which led to the symptoms resolving. -001
Information received by Monsanto indicates that proper personal protective equipment (PPE) was not being used. Monsanto has classified these three incidents as H-C. This third party seed treater also reported that a fourth individual alleged rash and respiratory symptoms allegedly associated with exposure to tioxazafen. This individual was also cleaning a seed treater system. This individual has received and continues to receive medical treatment. Information received by Monsanto indicates that proper PPE was not being used. Monsanto has classified this incident as H-B due to the ongoing nature of the treatment.

Two cases of alleged tioxazafen exposure were reported from individuals who were conducting re-piping work on seed treater pump equipment. Monsanto has classified both incidents as H-C incidents. One individual reportedly developed rash symptoms several days after alleged exposure. The individual was reportedly wearing PPE, but the PPE was torn. Symptoms did not resolve with a single treatment of prednisone, so the individual received additional medical treatment and another course of steroid treatment. At Monsanto's last knowledge, the rash was improving but had not resolved. The second individual experienced a rash as well and was given a course of steroid treatment. It is unclear whether

proper PPE was being used. At Monsanto's last knowledge, the symptoms had not completely resolved but the treatment was also not yet completed.

One case of alleged tioxazafen exposure was reported by a laboratory employee doing imaging work with a microscope. The employee alleged itchiness (but no rash) on her torso, neck and face, as well as hoarseness. The employee received prescription steroid and steroid cream treatment. Monsanto has classified this incident as H-C.

An individual working with treated seed alleged that she developed a rash and itching on her arms after exposure to tioxazafen, and later that day developed itchiness (but no rash) on her legs. Information received by Monsanto indicates that proper PPE was not being used. The individual was treated with steroids and the rash resolved, although the individual reports some discoloration of the skin. Monsanto has classified this incident as H-C.

Two individuals working at a third party seed treatment facility have alleged rashes on their arms and itchiness on the legs relating to exposure while working on a treated seed packaging line. It is not clear whether proper PPE was being used. Although one of these incidents occurred in November 2017, Monsanto is reporting the incident now. Monsanto has classified these incidents as H-C incidents.

While Monsanto continues to collect information with regard to these incidents and evaluate whether the symptomology reported to us is related to tioxazafen, we have reinforced, and continue to reinforce, the importance of proper PPE use in seed treatment operations.

If there are questions about this report, please contact James Nyangulu at (202) 383-2866 or by email at james.m.nyangulu@monsanto.com, or me directly at (314) 694-1538 or by email at simone.seifert-higgins@monsanto.com.

Sincerely,

Simone Seifert-Higgins

Simone Seifert-Higgins, Ph.D.
Regulatory Affairs Manager
Monsanto Company
US Chemical Regulatory Affairs

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name **Simone Seifert-Higgins**	Submission date. **December 1, 2017**	Contact person (if different than reporter) **Joy Thompson**	Internal ID **32442633, 32442695, 32442697, 32442698**
	Address **Monsanto Company** **Mail Stop C3NA** **800 N Lindbergh Blvd.** **St. Louis, MO 63167**		Address **Missouri Regional Poison Center (MRPC)** **7980 Clayton Road, Suite 200** **St. Louis, MO 63117**	
	Phone # **(314) 694-1538**		Phone # **(314) 772-8300**	
	Incident Status: New _X_ Update__ If update, include date of original submission.	Location and date of incident. (City, County, State) **State: Indiana** **Date: 10/20/2017**	Date registrant became aware of incident. **November 2017**	Was incident part of larger study? Y___N **_X_**U___

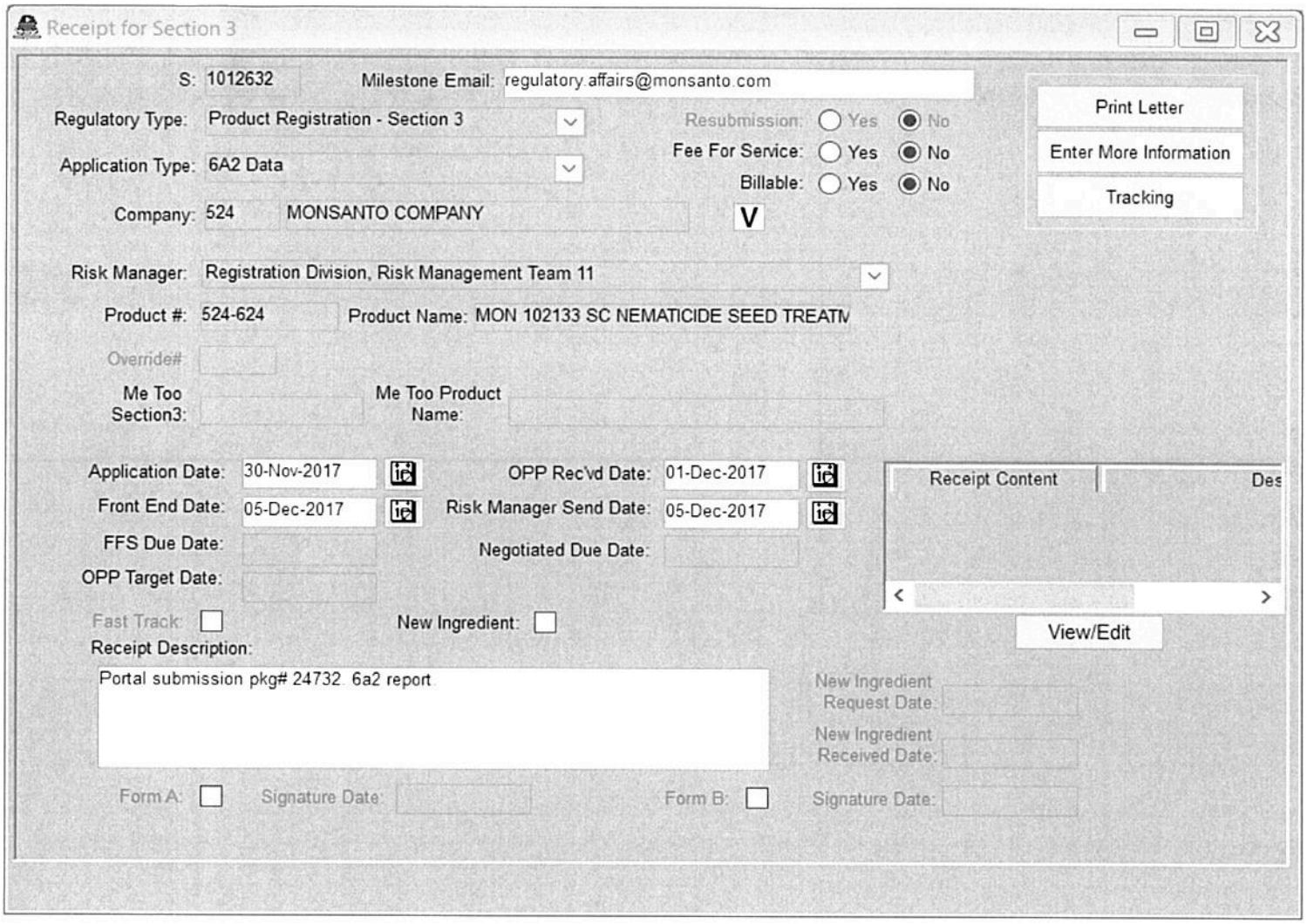
Row 2 Pesticide(s) Involved	**EPA Registration # (Product 1)** **524-624**	**EPA Registration # (Product 2)**	**EPA Registration # (Product 3 & 4)**
	A.I. (s) **Tioxazafen 45.88%**	A.I. (s)	A.I. (s)
	Product 1 Name **Acceleron Nemastrike ST**	Product 2 Name	Product 3&4 Name
	Exposed to concentrate prior to dilution? Y__N__U_**X**_NA__	Exposed to concentrate prior to dilution? Y__N__U__NA__	Exposed to concentrate prior to dilution? Y__N__U__NA__
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Yes_ __ No_**N**__U_ Intentional misuse_**No**_ Applicator certified PCO? Yes__No__U__**X**	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway). **Agricultural (corn)**	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). **See MRPC incident report (next page)**
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) **See MRPC incident report (next page)**	Brief description of incident circumstances. **See MRPC incident report (next page)**	

Human Exposure / Adverse Effect Incidents
Involving Monsanto Agricultural Products

Reporting Categories: H-A, H-B, H-C
Reporting Period: October 1, 2017 – October 31, 2017

Substance:	Acceleron Nemastrike ST from Monsanto
Serial Number:	32442633, 32442695, 32442697, 32442698
Date:	10/20/2017
Medical Outcome:	Moderate Effect H-C
EPA Reg. No.	524-624
Active Ingredients:	Tioxazafen 45.88%
State:	Indiana
History and Notes:	Man states he works with Nemastrike product and was initially exposed to dust about 30 days ago. He states a total of 4 people, where he works, were exposed. He normally wears PPE equipment, goggles and gloves. He does not wear a respirator. He works in processing seed. The corn seed is put inside a machine where the chemical is applied and dried on a conveyor system. The corn seed is then put in bags. The area where he works has a dust collecting system. The last time he worked was September 27th. He was exposed to dust about 5 to 6 times total. Since then, the facility has been cleaned. He has been to the MD and ED several times, started on steroids (3 rounds). Every time he stops the steroids, his symptoms return. He has clusters of hives, which gradually look like one solid rash. He states all 4 people exposed, came down with similar symptoms. Initially no respiratory symptoms. He states respiratory symptoms started later, approximately October 7th. MRPC discussed the product toxicity. Unknown possible allergic, sensitivity reaction to pesticide causing rash, hives. The man is under the care of his MD for continuing symptoms. Medical toxicologist at the company of product contacted in regard to the man's recurring symptoms. Medical toxicologist was able to contact the man and answer further questions from the caller. The company is handling the case of this caller and his co-workers.


Receipt for Section 3
S: 1012632
Milestone Email: regulatory.affairs@monsanto.com
Regulatory Type: Product Registration - Section 3
Application Type: 6A2 Data
Company: 524 MONSANTO COMPANY
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 11
Product #: 524-624
Product Name: MON 102133 SC NEMATICIDE SEED TREATM
Override#
Me Too Section3:
Me Too Product Name:
Application Date: 30-Nov-2017
OPP Rec'vd Date: 01-Dec-2017
Front End Date: 05-Dec-2017
Risk Manager Send Date: 05-Dec-2017
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Portal submission pkg# 24732. 6a2 report
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date: